The United States of America, by and through Jeffrey C. Sullivan, United States Attorney for the Western District of Washington, and Susan Loitz, Assistant United States Attorney for said District, hereby files its Sentencing Memorandum regarding defendants Donald Brandt and Sharon Brandt.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. The Charges.

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Defendants Donald and Sharon Brandt were jointly charged by Indictment with two felony crimes involving introducing into Interstate Commerce misbranded and adulterated medical devices. Because it was alleged that they acted with the intent to defraud or deceive, these charges in the Indictment were felonies. In addition, they were charged with the felony charge of conspiring to cause misbranded and adulterated medical devices to be shipped in interstate commerce.

However, as a result of a negotiated settlement, the Defendants each pled guilty to a single misdemeanor count in a Superseding Information: Causing the Introduction of an Adulterated Medical Device into Interstate Commerce. This charge relates to the

Vibe Machine, one of the devices that was the subject of a felony count in the Indictment. The Vibe Machine has not been approved by the FDA, and there is no exemption from approval. Thus, the device is adulterated under the terms of FDA statutes.¹

The Superseding Information does not allege that the Defendants acted with the intent to defraud or mislead, and thus the crime for which the defendants are being sentenced is a misdemeanor. The maximum period of incarceration for the offense is one year, and the maximum fine is \$100,000. 21 U.S.C. § 331(a)(1); 18 U.S.C. §§ 3571(b)(1) and (5).

B. The Defendants' Conduct

To properly evaluate the appropriate application of the Sentencing Guidelines and the sentencing factors outlined in 18 U.S.C. § 3553(a), the court should give careful consideration to the context in which the misdemeanor violation occurred, as described in the Presentence Report.

As set forth in detail in the Presentence Report, the Brandts operated a clandestine "clinic" in Mt. Vernon, Washington. Though neither Donald Brandt nor Sharon Brandt were licensed medical providers, they purported to treat various ailments and diseases, ranging from back pain to hepatitis and cancer, using the Vibe Machine and other unapproved or misbranded devices.²

The Brandts reaped substantial monetary rewards from their operation of this illegal clinic. They routinely charged \$400 per session for patients with cancer and other life-threatening diseases, and scheduled such patients to come four times per week

¹A device is adulterated if it is classified under FDA regulations as a Class III device, it has not received FDA approval and is not exempt from the requirement of FDA approval. 21 USC § 351(f)(1). The Vibe Machine is a Class III device under 21 U.S.C. § 360c(f); the device did not receive FDA approval; and there is no exemption from the requirement of such approval.

²In addition to the Vibe Machine, other devices used by the Brandts at their "clinic" were adulterated (e.g., the Multi-Wave form generators referred to in the Indictment), and misbranded (e.g., the Electro-Acuscope referred to in the Indictment).

for multiple weeks. The Brandts charged patients with more routine ailments \$50 per session and saw them less frequently. The Brandts did not bill insurance plans, accepting payments only from patients. Some patients reported receiving some treatments at discount rates or at no cost. The Brandts also made money by selling supplements at their clinic.

The extent of the Brandts' financial gains remains unknown, as the Brandts did not keep track of payments received for treatment of patients or for the sale of supplements, nor did they file tax returns reporting any income. However, at the request of the FDA, Madison & Associates prepared a financial analysis based on patient records seized from the Brandts' clinic. That analysis counted the number of treatments (as represented by treatment sheets in the patient files) multiplied by the typical charge of \$400 per session for cancer and hepatitis patients and \$50 per session for patients complaining of other ailments and diseases. That analysis resulted in a figure exceeding \$800,000 for a ten year period. This analysis did not, however, take into account reports that some treatments were free or provided at a reduced rate.³

Some witnesses reported that the Brandts made representations that the treatments would "clear" or cure their cancer. Several witnesses reported that Sharon Brandt mentioned specific high cure rates for cancer and hepatitis, and that the Brandts periodically assured them that their conditions were improving. Some patients and family members reported that the Brandts advised that they discontinue conventional medical treatments while receiving treatments from the Brandts. Numerous witnesses reported that the Brandts made efforts to keep their operations secret, by requesting that

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³It should also be noted that the financial analysis by Madison and Associates was based only on patient files seized from the clinic at the time of the search warrant. These files may not have included all patients treated by the Brandts.

they keep quiet about their treatments so that authorities, including the FDA, would not learn what they were doing.⁴

The Brandts' efforts to keep their operations secret were confirmed by Washington Department of Health investigators, and by a Mt. Vernon police officer. The Mt. Vernon police officer had been asked by an out-of-state law enforcement officer who was considering coming to the Brandts' clinic for treatment of his cancer, whether there had been any reports of Donald Brandt engaging in fraud. When questioned by the Mt. Vernon police officer, Donald Brandt denied that he was treating patients.

Several witnesses reported that Donald Brandt said he had once been a medical doctor, but had left the traditional practice of medicine to explore non-traditional medicine.

II. PROCEDURAL REQUIREMENTS IN SENTENCING

In imposing sentence, the court must properly calculate the Guidelines range, but cannot treat the Guidelines as mandatory. *Gall v. United States*, 128 S. Ct. 586, 597 (2007). The court must also consider the § 3553(a) factors, and adequately explain the sentence, including any deviation from the Guidelines range. *Id*.

If the court contemplates departing from the Sentencing Guidelines based on grounds for departure not identified in the presentence report or the parties' submissions, Federal Rule of Criminal Procedure 32(h) provides that it must give the parties reasonable notice that it is contemplating such a departure, and specify any ground on which the court is contemplating a departure. This requirement, however, applies only to non-Guidelines sentences imposed under the framework set forth in the Guidelines. It does not apply to variances under 18 U.S.C. § 3553(a). *United States v. Irizarry*, 128 S. Ct. 2198, 2203-04 (2008).

⁴In *United States v. Cambra*, 933 F.2d 752 (9th Cir. 1991), the court held that evidence that a defendant was trying to hide his activities from the FDA was a proper basis on which to find that the offense involved fraud and deceit.

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III. SENTENCING GUIDELINES ANALYSIS

Set forth below are Sentencing Guidelines provisions from Chapter One:
Authority and General Principles; Chapter Two: Offense Conduct; Chapter Three:
Adjustments; and, Chapter Five: Departures, that the government believes should be reviewed in connection with this sentencing.

A. Chapter One Provisions:

Section § 1B1.3, titled "Relevant Conduct (Factors that Determine the Guidelines Range)," provides in pertinent part that cross references in Chapter Two and adjustments in Chapter Three shall be determined on the basis of the following:

- (1) (A) all acts and omissions committed, aided, abetted, counseled, commanded, induced, procured, or willfully caused by the defendant; and
 - (B) in the case of a jointly undertaken criminal activity (a criminal plan, scheme, endeavor, or enterprise undertaken by the defendant in concern with others, whether or not charged as a conspiracy), all reasonably foreseeable acts and omissions of others in furtherance of the jointly undertaken criminal activity,

that occurred during the commission of the offense of conviction, in preparation for that offense, or in the course of attempting to avoid detection or responsibility for that offense;

* * *

- (3) all harm that resulted from the acts and omissions specified in subsections(a)(1) and (a)(2) above, and all harm that was the object of such acts and omissions; and
- (4) any other information specified in the applicable guideline.

The court's discretion to consider a wide range of information in fashioning a sentence is further made clear in Section 1B1.4 of the Guidelines:

"In determining the sentence to impose within the guideline range, or whether a departure from the guidelines is warranted, the court may consider, without limitation, any information concerning the background, character and conduct of the defendant, unless otherwise prohibited by law."

See also, United States v. Moreno-Hernandez, 48 F.3d 1112 (9th Cir. 1995) (in computing proper sentence, court is not precluded from looking to characteristics and conduct not encompassed within elements of crime of conviction).

B. Chapter Two Provisions

The table at Appendix A of the United States Sentencing Guidelines lists 2N2.1 as the applicable Guideline Section for a violation of 18 U.S.C. 331(a).

The Base Offense Level for this violation is 6.

Application Note 2N2.1 states that if the offense involved fraud, the court should apply USSG § 2B1.1 (Theft, Property Destruction, and Fraud). Although the Brandts were originally charged with committing misbranding and adulteration offenses with the intent to defraud and deceive, the charge to which they pled guilty does not include the fraud/deceit element. Accordingly, § 2B1.1 should not be used for calculating the offense level. *United States v. Takahashi*, 205 F.3d 1161, 1167 (9th Cir. 2000) (relevant conduct may not be used to select a guideline under 1B1.2). However, fraudulent conduct may be considered in the imposition of guidelines enhancements and adjustments, once a guideline has been selected. *See, Takahashi* at 1167. Such conduct may also be considered in connection with a departure from the Guidelines. USSG § 1B1.4.

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C. Chapter Three Provisions

Section 3A1.1(b) of the Guidelines provides for an enhancement of 2 or 4 points if victims of the offense were vulnerable:

- "(1) If the defendant knew or should have known that a victim of the offense was a vulnerable victim, increase by 2 levels.
- (2) If (A) subdivision (1) applies; and (B) the offense involved a large number of vulnerable victims, increase the offense level determined under subdivision (1) by 2 additional levels."

Application Note 2 to this Section defines a "vulnerable victim" as a person "(A) who is a victim of the offense of conviction and any conduct for which the defendant is accountable under 1B1.3 (Relevant Conduct) and (B) who is unusually vulnerable due to age, physical or mental condition, or who is otherwise particularly susceptible to the criminal conduct." The Application Note further states that "Subsection (b) applies to offenses involving an unusually vulnerable victim in which the defendant knows or should have known of the victim's unusual vulnerability. The adjustment would apply, for example, in a fraud case in which the defendant marketed an ineffective cancer cure"

Patients of the Brandts, particularly those with cancer and other serious diseases, are properly considered as vulnerable victims, under the Sentencing Guidelines definition. The points for vulnerable victims are properly added to the Guideline calculation pursuant to the directive in USSG § 1B.1.3(a), that relevant conduct can be used to determine appropriate adjustments under Chapter Three of the Guidelines.

The impact on vulnerable people was reported in multiple victim impact statements. Parents of a woman who died of cancer state: "We paid a total of \$20,000 or more to take her to Mt. Vernon WA for treatment. The last time we were there the Brandts told our daughter she was cancer free...But they lied to her....We would have done everything possible to save her life! She died a week before Christmas 2004."

One gentlemen writes that he and his wife paid the Brandts \$6,663.70: "I and my wife's life were impacted greatly by the financial burdens and the Brandts' false hope

of healing which also delayed other treatments which we will never know how that would have impacted the cancer or her recovery." Two others whose spouses died shortly after the Brandts' treatments report they paid \$4500 and \$4800 respectively, for three weeks of treatments. Another whose spouse died several months after the Brandts' treatments paid \$8,000, plus airfare and lodging expenses. She reports:

"These treatments and false hopes added immeasurable stress to an already dire situation. The Brandts misrepresented themselves and their clinic and preyed on the desperation of people with extremely serious illnesses." Another whose spouse died after receiving the Brandts' treatments believes the Brandts "were taking advantage of people at their most vulnerable time . . . we were ready to grasp at any straw that might help [my husband's] situation."

D. Resulting Guidelines Offense Level

Given the conduct as described in the Presentence Report, the Base Offense Level of 6 should be increased by 4 points because of the large number of vulnerable victims, for a resulting Offense Level of 10. If the court determines that the Defendants have clearly accepted responsibility for their offense, the Defendants' Offense Level would be 8, pursuant to the provisions of USSG § 3E1.1(a). This results in an advisory Guidelines Range of 0-6 months.

The court should reject Sharon Brandt's claim that she played a minor role in the offense. As described in the Presentence Report, she was an equal partner with Donald Brandt in the operation of the clinic. She made many of the false assurances of cure rates, and many of the requests that patients keep quiet about their treatments so that the clinic could remain free of regulatory oversight and law enforcement scrutiny.

E. Chapter Five: Part K Departures

There are bases on which the court could reasonably depart upward, and impose a sentence above the advisory range. For example, the policy statement set forth in USSG § 5K2.21, entitled "Dismissed and Uncharged Conduct" provides that "[t]he court may depart upward to reflect the actual seriousness of the offense based on

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conduct (1) underlying a charge dismissed as part of a plea agreement in the case, or underlying a potential charge not pursued in the case as part of a plea agreement or for any other reason; and (2) that did not enter into the determination of the applicable guideline range."

In addition, Application Note 3 to § 2N2.1 (the section that provides the base offense level for a misdemeanor adulteration charge) provides that "[i]f death or bodily injury, extreme psychological injury, property damage or monetary loss resulted, an upward departure may be warranted."

The Defendants' fraudulent conduct, though not an element of the misdemeanor charge to which they have pled guilty, can be grounds for an upward departure from the advisory Guideline Range. The monetary gain they achieved, though not part of the calculation of the advisory Guideline Range, can be also be grounds for an upward departure from that range.

IV. STATUTORY FACTORS TO BE CONSIDERED IN SENTENCING

In imposing a sentence sufficient, but not greater than necessary, the court is to consider "the nature and circumstances of the offense and the history and characteristics of the defendant," as well as the factors set forth in 18 U.S.C. §3553(a)(2). Those factors include the need for the sentence imposed:

- (A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense;
- (B) to afford adequate deterrence to criminal conduct; and
- (C) to protect the public from further crimes of the defendant.

In addition, the court should consider the defendant's ongoing need for medical care. 18 U.S.C. § 3553(a)(2)(D).

V. SENTENCING RECOMMENDATION

The government recommends a sentence of 6 months incarceration for each defendant, and the imposition of a fine of \$50,000.00, with each defendant jointly and

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severally responsible for payment of the fine. The sentences should also include a one year term of supervised release with the conditions recommended by Probation.

For years, the Brandts have demonstrated a disrespect for the law. They operated a clinic at which they practiced medicine without a license, using misbranded and adulterated devices. They failed to file income tax returns and paid no taxes on the financial gains from their illegal operations. This was serious conduct, with serious consequences for many people.

The Brandts took advantage of many very sick people who desperately sought some hope as they were dying, taking thousands of dollars from them in their last days. Though the Brandts profess they just wanted to just help people, their professed altruism is belied by the amount they charged. If their motives were purely altruistic, they would have charged cancer patients the same \$50 fee they asked of less sick people. Instead, they charged the seriously ill patients, many of whom were expected to die soon, \$1600 a week, for multiple weeks.

The Brandts are certainly not the only ones who have made money by operating "medical" practices without medical licenses, and without oversight by state and local health departments and licensing agencies or the FDA. A sentence of incarceration and a substantial fine will be a just punishment for the Brandts' conduct, will promote

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1	respect for the law, and will send a deterrent message to others with similar operations
2	that acting in disregard of such legitimate oversight comes with a price.
3	DATED this 14th day of August, 2008.
4	Respectfully submitted,
5	JEFFREY C. SULLIVAN United States Attorney
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CERTIFICATE OF SERVICE

I hereby certify that on August 14, 2008, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to the attorney(s) of record for the defendant(s). I hereby certify that I have served the attorney(s) of record for the defendant(s) that are non CM/ECF participants via telefax.

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